

REMARKS

1. Claim Rejections under 35 U.S.C. § 112, First Paragraph.

Claims 1 and 9 stand rejected under 35 U.S.C. § 112, first paragraph (“Section 112”) for failing to comply with the written description requirement.

The “fundamental factual inquiry [in making a Section 112, first paragraph rejection] is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” See MPEP § 2163(I)(B). Compliance with the written description requirement requires that “each claim limitation . . . be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.” See MPEP § 2163(II)(A)(3)(b)(internal quotes omitted).

Applicant respectfully submits that rejected claims 1 and 9 find adequate support in the specification originally filed and therefore comply with the requirements of Section 112. Specifically, a person of ordinary skill in the art would have understood, at the time the application was filed, that the description of embodiments of the invention that “include the consumption of more than one fluid ounce per day” (see Specification, p. 16, ln. 3) inherently include consumption of three fluid ounces per day. Contrary to the Examiner’s assertion, “more than one fluid ounce” necessarily includes three ounces.

In light of the foregoing, Applicant respectfully submits that the rejected claims do not constitute new matter and accordingly requests withdrawal of the Examiner's rejections of claims 1 and 9 under Section 112.

2. Claim Rejections under 35 U.S.C. § 112, Second Paragraph.

Claims 1, 7 and 25 stand rejected under 35 U.S.C. § 112, second paragraph ("Section 112, Paragraph 2") as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response to the Examiner's assertion that the percent range for *Morinda citrifolia* fruit juice present in the supplement is indefinite in light of the claimed additional ingredient, Applicant has amended claim 1 to recite "*Morinda citrifolia* fruit juice present in an amount between about 10 and 99.99 percent by weight." This amendment adds no new matter as it finds adequate support in the specification originally filed.

Claims 7 and 25 add further limitations to otherwise allowable subject matter and are thus also not indefinite under Section 112, Paragraph 2. Accordingly, Applicant respectfully requests withdrawal of the Examiner's rejections of claims 1, 7 and 25 under Section 112, Paragraph 2.

3. Claim Rejections under 35 U.S.C. § 103(a).

Claims 1, 4-12, 24 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mumford (1998) in view of Brock (1991), in view of Gagnon (1997), and further in view of European Patent No. 555,573 A1 to Nahir ("Nahir").

An invention is unpatentable under Section 103 "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would

have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.”

To establish a *prima facie* case of obviousness, three criteria must be met. “First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” MPEP § 2142.

A “clear and particular” showing of the suggestion to combine or modify is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant’s claims are not obvious in view of the prior art references.

Applicant’s claim 1 recites a method comprising “consuming on an empty stomach each day to inhibit, prevent, and reverse lipid peroxidation, three ounces of a dietary supplement comprising *Morinda citrifolia* fruit juice.” As no cited reference discloses nor suggests consumption of a *Morinda citrifolia*-containing supplement to inhibit, prevent and reverse lipid peroxidation, the present invention is not obvious in view of such references.

Indeed, Mumford discloses consuming *Morinda citrifolia* fruit juice to treat migraine headaches, increase energy levels and inhibit susceptibility to the common cold. Mumford also discloses topically applying *Morinda citrifolia* leaves to reduce pain. (See Mumford, p. 1-2). Mumford neither discloses nor suggests consuming *Morinda citrifolia* fruit juice to inhibit, prevent or reverse lipid peroxidation.

A “*prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties.” See MPEP § 2144.09. In this case, the present application indicates consumption of three ounces of a dietary supplement containing *Morinda citrifolia* fruit juice to inhibit, prevent and reverse lipid peroxidation. Such use of *Morinda citrifolia* fruit juice is neither expressly indicated nor suggested by Mumford or any other cited reference. Indeed, Mumford emphasizes consumption of *Morinda citrifolia* fruit juice to reduce the occurrence and/or severity of migraine headaches, among other ailments. In so doing, Mumford teaches away from the present invention. In addition, the present invention comprises unexpectedly advantageous properties in view of Mumford.

Indeed, migraine headaches are caused by vasoconstriction of blood vessels in the brain, leading to hypoxia of the vascular system. Hypoxia is defined as inadequate oxygenation that causes a deficiency of oxygen in reaching the tissues of the body. Reducing the severity and/or frequency of migraine headaches thus requires increasing oxygenation to reverse hypoxic effects. The present invention, on the other hand, seeks to reduce free radicals in the body, which are caused by oxygenation. Accordingly, the present invention teaches consuming a *Morinda citrifolia*-containing supplement to reduce oxygenation and, hence, the production of free radicals. As the prior art teaches that reducing oxygenation exacerbates migraine headaches, one skilled in the art would not be motivated by Mumford to modify the invention disclosed therein to inhibit, reverse and prevent lipid peroxidation as claimed by the present invention since reducing oxygenation would vitiate the purpose of Mumford in reducing the frequency and severity of migraine headaches.

Mumford further fails to disclose or suggest consuming three ounces of a supplement containing *Morinda citrifolia* fruit juice to inhibit reverse and prevent lipid peroxidation, and specifically teaches away from such a dosage by emphasizing the beneficial effects of consuming only one to two ounces of the juice. One skilled in the art would not be motivated by Mumford to consume more than two ounces of the juice where Mumford emphasizes that only one ounce of the juice is sufficient to make one “feel better.” (See Mumford, p. 1).

As the cited references fail to disclose or suggest all of the present claim limitations, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

Further, as claims 4-12, 24 and 26 depend from otherwise allowable subject matter, such claims are also not obvious in view of the cited references.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 4-12, 24 and 26 under Section 103.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,

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